

# Genetically Engineered Fish and Seafood: Environmental Concerns

Updated February 20, 2013

Congressional Research Service

<https://crsreports.congress.gov>

R41486

## Summary

In the process of congressional oversight of executive agency regulatory action, concerns have been raised about the adequacy of the FDA's review of a genetically modified (GM) salmon. More specifically, concern has focused on whether and how potential environmental issues related to this GM salmon might be addressed. In response to these concerns, several bills were introduced in the 112<sup>th</sup> Congress seeking to declare GM fish unsafe and thus prevent FDA approval of this salmon for human consumption or to require that GM fish be specifically labeled. No final action was taken on these bills by the 112<sup>th</sup> Congress.

Genetic engineering techniques allow the manipulation of inherited traits to modify and improve organisms. Several GM fish and seafood products are currently under development and offer potential benefits such as increasing aquaculture productivity and improving human health. However, some are concerned that, in this rapidly evolving field, current technological and regulatory safeguards are inadequate to protect the environment and ensure public acceptance that these products are safe for consumption. (The safety of GM foods for human consumption is not addressed in this report.)

In the early 2000s, several efforts began to develop GM fish and seafood products, with a GM AquAdvantage salmon developed by AquaBounty, Inc., in the forefront of efforts to produce a new product for human consumption. By September 2010, requested data had been provided to the U.S. Food and Drug Administration (FDA) by AquaBounty, and FDA's Veterinary Medicine Advisory Committee held public hearings on the approval of AquAdvantage salmon for human consumption. The public comment period on FDA approval closed on November 22, 2010.

Environmental concerns related to the development of GM fish include the potential for detrimental competition with wild fish, and possible interbreeding with wild fish so as to allow the modified genetic material to escape into the wild fish population. Sterilization and bioconfinement have been proposed as means of isolating GM fish to minimize harm to wild fish populations. To address these concerns, AquaBounty proposed producing salmon eggs (all sterile females) in Canada, shipping these eggs to Panama, growing and processing fish in Panama, and shipping table-ready, processed fish to the United States for retail sale.

On December 20, 2012, FDA announced the availability for public comment of (1) a draft environmental assessment of the proposed conditions specified by AquaBounty and (2) FDA's preliminary finding of no significant impact (FONSI) for AquaBounty's conditions. A 60-day public comment period initially ran through February 25, 2013, but was extended through April 26, 2013. If significant new information or challenges arise in the public comments, FDA must decide whether or not a full environmental impact statement is required prior to approval of AquaBounty's application. If approved, AquAdvantage salmon would be the first GM animal approved for human consumption.

## **Contents**

Background .....	1
Environmental Concerns and Control Options.....	2
Concerns.....	2
Interbreeding with Wild Fish .....	3
Competition with Wild Fish.....	3
Potential Control Options.....	4
Sterilization .....	4
Confinement.....	4
Other Possible Benefits and Disadvantages of Genetically Engineered Fish and Seafood.....	5
Potential Benefits .....	5
Disadvantages .....	5
Regulation and Recent Action .....	6
Congressional Interest .....	8

## **Contacts**

Author Information.....	8
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Farmers and scientists have a history of modifying animals to maximize desirable traits. Genetic modification is one of the current approaches for modifying animals to increase their beneficial traits. In the broadest sense, genetic modification refers to changes in an organism's genetic makeup not occurring in nature, including the production of conventional hybrids. With the advent of modern biotechnology (e.g., genetic engineering or bioengineering), it is now possible to take the gene (or genes) for a specific trait either from an organism of the same species or from an entirely different one and transfer it to create an organism having a unique genetic code. This technique can add both speed and efficiency to the development of new foods and products. Genetically engineered plant varieties, such as herbicide-resistant corn and soybeans, have already been widely adopted by U.S. farmers, and some advocate using similar techniques to produce genetically engineered fish or seafood for the aquaculture industry.

A number of environmental concerns have been raised related to the development of genetically modified (GM) fish, including the potential for detrimental competition with wild fish, and possible interbreeding with wild fish so as to allow the modified genetic material to escape into the wild fish population. Sterilization and bioconfinement have been proposed as means of isolating GM fish to minimize the potential for harming wild fish populations.

In the process of congressional oversight of executive agency regulatory action, concerns have been raised about the adequacy of the U.S. Food and Drug Administration's review of applications for approval of GM animals, with respect to the potential for environmental harm.<sup>1</sup> In response to these concerns, several bills were introduced in the 112<sup>th</sup> Congress seeking to declare GM fish unsafe or require that GM fish be specifically labeled as such. No final action was taken on these bills in the 112<sup>th</sup> Congress.

## Background

Scientists are seeking ways to genetically engineer fish and other seafood species to introduce or amplify economically valuable traits. Fish are of particular interest to food researchers since many fish produce large quantities of eggs; those eggs, being external to the animal (as opposed to mammals that produce a few eggs internally), make it relatively simple to insert novel DNA.

Research on transgenic strains is currently under development for at least 35 species of fish worldwide, as well as for a variety of mollusks, crustaceans, plants, and marine microorganisms.<sup>2</sup> Fish are being modified to improve the production of human food, to produce pharmaceuticals, to test water contamination, and for other uses.<sup>3</sup>

The U.S. Food and Drug Administration (FDA) regulates GM fish under the Federal Food, Drug, and Cosmetics Act (FFDCA)<sup>4</sup> provisions on new animal drugs (21 U.S.C. §321).<sup>5</sup> Under these

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<sup>1</sup> This CRS report does not consider the food safety of GM fish; for background on food safety regulation, see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Renée Johnson.

<sup>2</sup> For additional background on genetic engineering in animals, see [http://www.cast-science.org/publications/?the\\_science\\_and\\_regulation\\_of\\_food\\_from\\_genetically\\_engineered\\_animals&show=product&productID=21628](http://www.cast-science.org/publications/?the_science_and_regulation_of_food_from_genetically_engineered_animals&show=product&productID=21628).

<sup>3</sup> For a list of some of the genetically engineered organisms under research, see Table 2-2 in National Research Council, *Animal Biotechnology: Science-Based Concerns* (Washington, DC: National Academies Press, 2002), <http://books.nap.edu/books/0309084393/html/73.html#pagetop>.

<sup>4</sup> 21 U.S.C. §§301 et seq.

<sup>5</sup> For additional background on FDA regulation of genetically engineered animals, see <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048106.htm>.

provisions, FDA must keep all information about a pending drug application confidential, with the exception of information publicly disclosed by the manufacturer. This approach limits the opportunity for public comment before approval. Some critics are calling for more transparency in this process and for more authority to be given to environmental and wildlife agencies.<sup>6</sup>

One GM fish has been marketed to date. Glofish™, a genetically altered version of the popular aquaria zebrafish (*Danio rerio*), fluoresce after the insertion of a sea anemone gene into the zebrafish egg.<sup>7</sup> This fish is currently legal to be sold in all states except California. Since Glofish™ are not meant for human consumption, FDA determined that the Glofish™ was not under its jurisdiction.<sup>8</sup>

Another private research company has taken genetic information from Chinook salmon and ocean pout (an eel-like, edible fish) and inserted this material into Atlantic salmon to create a fish that grows to market size twice as fast as its non-GM counterparts. This company, AquaBounty Technologies, Inc., is currently seeking regulatory approval from the FDA to sell its AquAdvantage salmon for human consumption in the United States<sup>9</sup> and received a grant from the U.S. Department of Agriculture's National Institute of Food and Agriculture for work on transgenic tilapia.<sup>10</sup> Other examples of GM fish that have been developed, but for which regulatory approval has not yet been sought, include fish that would produce a blood-clotting factor to treat individuals with hemophilia<sup>11</sup> and disease-resistant channel catfish.<sup>12</sup>

## Environmental Concerns and Control Options

### Concerns

In addition to its responsibility for assuring food safety, FDA is charged with assessing the potential environmental impacts of newly engineered plants and animals. To fully assess these potential impacts, FDA consults with the Fish and Wildlife Service and the National Marine Fisheries Service (NOAA Fisheries).<sup>13</sup> Despite this consultation, critics question whether FDA has the mandate and sufficient expertise to identify and protect against all potential ecological damage that might result from the widespread use of transgenic fish.<sup>14</sup>

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<sup>6</sup> Union of Concerned Scientists, "Risks of Genetic Engineering," [http://www.ucsusa.org/food\\_and\\_agriculture/science\\_and\\_impacts/impacts\\_genetic\\_engineering/risks-of-genetic-engineering.html](http://www.ucsusa.org/food_and_agriculture/science_and_impacts/impacts_genetic_engineering/risks-of-genetic-engineering.html).

<sup>7</sup> Yorktown Technologies, L.P., <http://www.glofish.com/>.

<sup>8</sup> For the FDA statement regarding Glofish, see <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm106233.htm>.

<sup>9</sup> AquaBounty Technologies, Inc., <http://www.aquabounty.com/>.

<sup>10</sup> See [http://www.nifa.usda.gov/newsroom/news/2011news/brag\\_awards.html](http://www.nifa.usda.gov/newsroom/news/2011news/brag_awards.html).

<sup>11</sup> Amitabh Avasthi, "Can Fish Factories Make Cheap Drugs?" *New Scientist*, vol. 183, no. 2464 (Sept. 11-17, 2004): 8.

<sup>12</sup> See Pew Initiative on Food and Biotechnology, "Harvest on the Horizon, Future Uses of Agricultural Biotechnology," [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food\\_and\\_Biotechnology/hhs\\_biotech\\_harvest\\_report.pdf](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Food_and_Biotechnology/hhs_biotech_harvest_report.pdf).

<sup>13</sup> 21 U.S.C. §2106 requires FDA to consult with NOAA to produce a report on any environmental risks associated with genetically engineered seafood products, including the impact on wild fish stocks. According to FDA, as of October 6, 2010, this report has not been completed and no target date for completion is specified (<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/SignificantAmendmentsstotheFDCA/FoodandDrugAdministrationAmendmentsActof2007/FDAImplementationChart/default.htm>).

<sup>14</sup> See the Center for Food Safety's "Genetically Engineered Fish," <http://www.centerforfoodsafety.org/genetical3.cfm>.

The possible impacts from the escape of GM organisms from aquaculture facilities are of great concern to some scientists and environmental groups.<sup>15</sup> A National Research Council report stated that transgenic fish pose the “greatest science-based concerns associated with animal biotechnology, in large part due to the uncertainty inherent in identifying environmental problems early on and the difficulty of remediation once a problem has been identified.”<sup>16</sup>

### **Interbreeding with Wild Fish**

Critics and scientists argue that GM fish could breed with wild populations of the same species and potentially spread undesirable genes. One study postulated a “Trojan gene hypothesis” after observing that GM Japanese medaka, a fish commonly used as an experimental model, were able to out-compete nonaltered fish for mates in a laboratory environment. However, the resulting offspring of this mating between GM fish and wild fish were less fit, lacking certain physical or behavioral attributes that resulted in the eventual demise of the modified population.<sup>17</sup>

The ecological risks of stocking GM shellfish in the wild have not yet been thoroughly examined, since confining and isolating these organisms is more difficult than confinement of many fish species, due to their methods of reproduction and dispersal.<sup>18</sup>

### **Competition with Wild Fish**

Even if fast-growing GM fish do not spread their genes among their wild counterparts, critics fear GM fish could disrupt the ecology of streams by competing with native fish for scarce resources. Escaped transgenic fish could harm wild fish through increased competition or predation. In addition, some argue that transgenic fish, especially if modified to improve their ability to withstand wider ranges of salinity or temperature, could be difficult or impossible to eradicate, similar to an invasive species. The consequences of such competition would depend on many factors, including the health of the wild population, the number and specific genetic strain of the escaped fish, and local environmental conditions. Critics maintain that an indication of the magnitude of this potential problem may be noted where non-GM Atlantic salmon from nearshore net pens in the northwest United States<sup>19</sup> and British Columbia<sup>20</sup> have escaped and entered streams, in some cases outnumbering their wild Pacific salmon counterparts.

However, it is not known whether GM fish could survive in the wild in sufficient numbers to inflict permanent population damage. One study indicated that, when food supplies were low, GM fish might have the ability to harm a wild population, although the authors caution that laboratory experiments may not reflect what would happen in the wild.<sup>21</sup> Biotechnology proponents argue

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<sup>15</sup> See also Matthew Morgan, “The AquAdvantage Salmon: Who Owns Escaped Genetically Modified Animals?” *Ocean and Coastal Law Journal*, v. 17, no. 1 (2011): 127-161.

<sup>16</sup> National Research Council, *Animal Biotechnology: Science-Based Concerns* (Washington, DC: National Academies Press, 2004), [http://books.nap.edu/openbook.php?record\\_id=10418&page=R1](http://books.nap.edu/openbook.php?record_id=10418&page=R1).

<sup>17</sup> Richard D. Howard et al., “Transgenic Male Mating Advantage Provides Opportunity for Trojan Gene Effect in a Fish,” *Proceedings of the National Academy of Sciences*, vol. 101, no. 9 (March 2, 2004): 2934-2938, <http://www.pnas.org/cgi/reprint/101/9/2934.pdf>.

<sup>18</sup> Many shellfish, such as oysters, broadcast their eggs and sperm into the water column and have larvae that have a planktonic or swimming form, making them very difficult to contain in an open water pen.

<sup>19</sup> Washington Dept. of Fish and Wildlife, “Atlantic Salmon in Washington State,” <http://wdfw.wa.gov/publications/pub.php?id=00922>.

<sup>20</sup> The Alaska Fish and Game Dept. reports statistics on escaped and recovered Atlantic Salmon in Washington State, British Columbia, and Alaska, [http://www.adfg.state.ak.us/special/as/docs/esc\\_rec87-04.pdf](http://www.adfg.state.ak.us/special/as/docs/esc_rec87-04.pdf).

<sup>21</sup> Robert H. Devlin et al., “Population Effects of Growth Hormone Transgenic Coho Salmon Depend on Food

that GM fish, if they escape, would be less likely to survive in the wild, especially when they are reared in protected artificial habitats and have not learned to avoid predators.

## Potential Control Options

A number of potential safeguards to address these environmental concerns exist and could be required.

### Sterilization

FDA could require that only sterile GM fish be approved for culture. Fertilized fish eggs that are subjected to a heat or pressure shock retain an extra set of chromosomes. The resulting triploid fish do not develop normal sexual characteristics and, in general, the degree of sterility in triploid females is greater than males.<sup>22</sup> Thus, all-female lines of triploid fish are considered to be one of the best current methods to insure nonbreeding populations of GM fish. Nonetheless, there are batch-to-batch variations, and it is uncertain whether this method could be effective for all species; it has not been successful for shrimp, for example.<sup>23</sup> Also, critics question whether escaped triploid fish, which in some species have sufficient sex hormone levels to enable normal courtship behavior, could mate with wild individuals, lowering reproductive success of the wild population.<sup>24</sup>

Other sterilization methods are currently under study, and it is likely that research in this area will increase options. Critics of GM fish counter that the risks to native fish populations, however small, may outweigh the potential benefits of this technology, especially where native fish populations are already threatened or endangered.

### Confinement

To be most effective in reducing ecological risk, the National Research Council report on *Bioconfinement of Genetically Engineered Organisms* recommends that each individual species have its own bioconfinement<sup>25</sup> plan. Also, since no single method is likely to be 100% effective, bioconfinement redundancy significantly increases the likelihood of control, especially if it will not be combined with physical confinement. Growing GM marine fish in isolated onshore tanks rather than in offshore or nearshore pens may substantially lower the risk of escape into the wild.<sup>26</sup>

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Availability and Genotype by Environment Interactions,” *Proceedings of the National Academy of Sciences*, vol. 101, no. 25, pp. 9303-9308, (June 22, 2004), <http://www.pnas.org/cgi/content/abstract/101/25/9303>.

<sup>22</sup> Gary H. Thorgaard and Standish K. Allen, “Environmental Impacts of Inbred, Hybrid and Polyploid Aquatic Species,” in *Dispersal of Living Organisms into Aquatic Ecosystems* (Univ. of Maryland Sea Grant, 1992), pp. 281-288.

<sup>23</sup> National Research Council, *Bioconfinement of Genetically Engineered Organisms* (Washington DC: National Academies Press 2004), [http://books.nap.edu/openbook.php?record\\_id=10880&page=R1](http://books.nap.edu/openbook.php?record_id=10880&page=R1).

<sup>24</sup> See Darek T. R. Moreau, Corinne Conway, and Ian A. Fleming, “Reproductive Performance of Alternative Male Phenotypes of Growth Hormone Transgenic Atlantic Salmon (*Salmo salar*),” *Evolutionary Applications*, vol. 4 (2011): 736-748.

<sup>25</sup> Bioconfinement refers to biological methods, such as induced sterilization, used to confine GM organisms and their transgenes to their designated release setting.

<sup>26</sup> A federal biological opinion issued in November 2003 by the Fish and Wildlife Service and National Oceanic and Atmospheric Administration prohibited the use of GM salmon in open-water net pens pursuant to the Endangered Species Act; see <http://stopgefish.files.wordpress.com/2010/10/corp-bo-full-file.pdf>.



## Other Possible Benefits and Disadvantages of Genetically Engineered Fish and Seafood

### Potential Benefits

Biotechnology proponents maintain that genetic modification techniques have many advantages over traditional breeding methods, including faster and more specific selection of beneficial traits. Because scientists are able to directly select traits they wish to create or amplify, the desired change can be achieved in very few generations, making it faster and lower in cost than traditional methods, which may require many generations of selective breeding. Genetic modification techniques allow scientists to precisely select traits for improvement, enabling them to create an organism that is not just larger and faster-growing, but potentially improved, for example, by increasing nutritional content.<sup>27</sup> Proponents claim that faster-growing fish could make fish farming more productive, increasing yields while reducing the amount of feed needed, which in turn could reduce waste. With intense exploitation of wild fish stocks, GM fish and seafood could be important means to meet increasing human nutrition needs and address food security concerns.

Shellfish and finfish, genetically modified to improve disease resistance, could reduce the use of antibiotics. Increased cold resistance in fish could lead to the ability to grow seafood in previously inhospitable environments, allowing aquaculture to expand into previously unsuitable areas. Research efforts are also under way to improve human health by genetically modifying fish to produce human drugs like a blood clotting factor and to create shellfish that will not provoke allergic reactions. Biotechnology proponents claim that these advantages could translate into a number of potential benefits, such as reduced costs to producers, lower prices for consumers for edible fish and pharmaceuticals, and environmental benefits, such as reduced water pollution from wastes. Food scientists and the aquaculture industry may support the introduction of genetic engineering, provided that issues of product safety, environmental concerns, ethics, and information are satisfactorily addressed.

### Disadvantages

On the other hand, while the majority of consumers in the United States appear to have generally accepted GM food and feed crops,<sup>28</sup> it is uncertain whether consumers will be as accepting of GM fish. Although such fish may taste the same and are expected, like their traditionally bred counterparts, to be less expensive than wild-caught fish, ethical concerns over the appropriate use of animals, in addition to environmental concerns, may affect public acceptance of GM fish as food. Ongoing campaigns by environmental and consumer groups have asked grocers, restaurants, and distributors to sign a pledge to not sell GM fish products, even if they are approved by FDA.<sup>29</sup>

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<sup>27</sup> This point is contested by some who cite research indicating nutritional deficiencies, including decreased omega-3 fatty acid content in cultured salmon fed an artificial diet high in vegetable protein. For example, see <http://www.whfoods.com/genpage.php?tname=george&dbid=96>.

<sup>28</sup> Thomas Hoban, "Trends in Consumer Attitude About Agricultural Biotechnology," *AgBioForum*, vol. 1, no. 1 (1998): 3-7, <http://www.agbioforum.org/v1n1/v1n1a02-hoban.htm>.

<sup>29</sup> See the Center for Food Safety's "Genetically Engineered Fish," <http://www.centerforfoodsafety.org/geneticall3.cfm>.



In addition, the commercial fishing industry says that it has successfully educated the public to discriminate among fish from different sources, such as wild and farmed salmon. It is possible that a publicized escape of GM fish could lead to reduced public acceptance of their wild product. Environmental and consumer groups are asking that genetically engineered products be specially labeled. However, industry groups are concerned that such labeling might lead consumers to believe that their products are unsafe for consumption.<sup>30</sup>

## Regulation and Recent Action

A National Research Council study maintains that there is a low to moderate food safety risk from GM seafood.<sup>31</sup> Since genetic engineering can introduce new protein into a food product, there are concerns that this technique could introduce a previously unknown allergen into the food supply or could introduce a known allergen into a “new” food. Within FDA, the Center for Veterinary Medicine regulates transgenic animals intended for human consumption under the same authority it uses to regulate new animal drugs.<sup>32</sup> In addition, GM fish must adhere to the same standards of safety under the FFDCA and the FDA’s Center for Food Safety and Applied Nutrition<sup>33</sup> that apply to conventionally bred fish. Under the adulteration provisions in Section 402(a)(1) of the FFDCA, FDA has the power to remove a food from the market or sanction those marketing the food if that food poses a risk to public health. This CRS report does not consider the food safety regulation of GM fish; for background on food safety regulation, see CRS Report RS22600, *The Federal Food Safety System: A Primer*, by Renée Johnson.

By early 2010, AquaBounty Technologies, Inc., had provided FDA with almost all of the data required by the agency to consider approving the company’s GM AquAdvantage salmon. The approval debate has focused on whether GM animals should be allowed, and if so, whether they should be labeled as such. The question of how to label the food derived from the AquAdvantage salmon is separate from the decision about whether to approve the new animal drug application. If the Commissioner determines that the new animal drug meets the approval standard, she “shall issue an order approving the application.”<sup>34</sup> Issues related to the question of whether a food from the AquAdvantage salmon is misbranded, based on its labeling, are separate. Although FDA is not required to address these issues prior to the food being marketed, FDA is considering these two issues simultaneously.<sup>35</sup>

The AquAdvantage salmon, all sterile females, are proposed to be grown only in isolated contained facilities, not in ocean pens that have a higher risk of escape into the wild. More specifically, AquaBounty has proposed producing eggs on Prince Edward Island, Canada,<sup>36</sup>

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<sup>30</sup> See CRS Report RL32809, *Agricultural Biotechnology: Background and Recent Issues*, by Tadlock Cowan.

<sup>31</sup> National Research Council, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, (Washington, DC: National Academies Press, 2004), [http://books.nap.edu/openbook.php?record\\_id=10977&page=R1](http://books.nap.edu/openbook.php?record_id=10977&page=R1).

<sup>32</sup> The FDA Center for Veterinary Medicine’s “Questions and Answers about Transgenic Fish,” <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm133255.htm>.

<sup>33</sup> FDA’s Center for Food Safety and Applied Nutrition administers the agency’s seafood inspection program; see <http://www.cfsan.fda.gov/seafood1.html>.

<sup>34</sup> 21 U.S.C. 360b(d)(1).

<sup>35</sup> FDA, “Background Document: The VMAC Meeting on Science-Based Issues Associated with AquAdvantage Salmon,” <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm222712.htm>.

<sup>36</sup> Questions have been raised concerning AquaBounty’s approval by Environment Canada for producing and

shipping these eggs to Panama, growing and processing the fish in Panama, and shipping table-ready, processed fish to the United States for retail sale. If approved, it could take two to three years for the AquaAdvantage salmon to reach supermarkets.<sup>37</sup> As a first step in the approval process, FDA held public hearings on AquaAdvantage salmon by its Veterinary Medicine Advisory Committee on September 19-21, 2010.<sup>38</sup> Although the public comment period on FDA approval was open through November 22, 2010, there was no deadline for FDA's decision on AquaBounty's application. Meanwhile, critics claimed the convoluted 16-year FDA review process was scientifically unjustified, and threatened to rob society of both environmental and economic benefits.<sup>39</sup>

In an effort to broaden the evaluation of the AquaBounty application, a coalition of environmental groups called on FDA to prepare an environmental impact statement (EIS) on this action and to consult with federal agencies about possible threats to endangered wild Atlantic salmon.<sup>40</sup> Subsequently, on May 25, 2011, these groups filed a formal citizen petition urging FDA to withhold approval until an EIS has been completed.<sup>41</sup> Some scientists also expressed concern for a broader evaluation, including pointing out that potential price decreases from technological innovation in producing GM fish could promote health benefits from increased consumption.<sup>42</sup> Concern has also increased in Canada over the possible effects of producing these GM fish.<sup>43</sup>

On December 20, 2012, FDA announced the availability for public comment of (1) a draft environmental assessment of the proposed conditions specified by AquaBounty<sup>44</sup> and (2) FDA's preliminary finding of no significant impact (FONSI)<sup>45</sup> for AquaBounty's conditions.<sup>46</sup> A 60-day public comment period initially ran through February 25, 2013, but was extended through April 26, 2013.<sup>47</sup> If significant new information or challenges arise in the public comments, FDA must decide whether or not a full EIS is required prior to approval of AquaBounty's application. If FDA approves AquaBounty's application, FDA retains the authority to withdraw its approval should significant concerns arise subsequently.

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transporting the GE salmon eggs. See <http://lists.cban.ca/pipermail/cban-e-news/2011-October/000346.html>.

<sup>37</sup> Andrew Pollack, "Genetically Altered Salmon Get Closer to the Table," *New York Times*, June 26, 2010, p. A1.

<sup>38</sup> Background documents for this public hearing are available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm201810.htm>. See also 75 *Federal Register* 52602-52605, August 26, 2010.

<sup>39</sup> See Alison L. Van Eenennaam and William M. Muir, "Transgenic Salmon: A Final Leap to the Grocery Shelf?" *Nature Biotechnology*, v. 29, no. 8 (August 2011): 706-710.

<sup>40</sup> [http://www.eenews.net/assets/2010/11/08/document\\_pm\\_01.pdf](http://www.eenews.net/assets/2010/11/08/document_pm_01.pdf).

<sup>41</sup> <http://earthjustice.org/news/press/2011/environmental-groups-petition-federal-government-to-complete-full-and-transparent-review-of-environmental-impact>.

<sup>42</sup> Martin D. Smith et al., "Genetically Modified Salmon and Full Impact Assessment," *Science*, v. 330 (November 19, 2010): 1052-1053.

<sup>43</sup> <http://www.thefishsite.com/fishnews/13771/coalition-demands-govt-openness-on-ge-salmon>; see also [http://www.montrealgazette.com/story\\_print.html?id=4330327&sponsor=](http://www.montrealgazette.com/story_print.html?id=4330327&sponsor=) and <http://www.newswire.ca/en/releases/archive/March2011/03/c7657.html>.

<sup>44</sup> Available at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333102.pdf>.

<sup>45</sup> Available at <http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/GeneticEngineering/GeneticallyEngineeredAnimals/UCM333105.pdf>.

<sup>46</sup> 77 *Federal Register* 76050 (December 26, 2012).

<sup>47</sup> 78 *Federal Register* 10620-10621 (February 14, 2013).

States have also taken steps to regulate the use and transport of GM fish. For example, Maryland,<sup>48</sup> Washington,<sup>49</sup> Oregon,<sup>50</sup> Minnesota,<sup>51</sup> Wisconsin,<sup>52</sup> and California<sup>53</sup> have passed laws banning the release of GM fish in some or all state waters. In addition, Alaska requires GM fish to be labeled.<sup>54</sup> No federal law specifically addresses GM fish and seafood.

## Congressional Interest

In the 112<sup>th</sup> Congress, several bills were introduced to address concerns related to GM fish. S. 229, H.R. 520, and H.R. 3553 would have amended the Federal Food, Drug, and Cosmetic Act to require labeling of genetically engineered fish. S. 230 and H.R. 521 would have amended the Federal Food, Drug, and Cosmetic Act to prevent the approval of genetically engineered fish for human consumption. Section 744 of H.R. 2112, as passed by the House on June 16, 2011, would have prohibited the Food and Drug Administration from spending FY2012 funds to approve any application for genetically engineered salmon.<sup>55</sup> On September 7, 2011, the Senate Committee on Appropriations reported H.R. 2112, without the prohibition on FDA related to genetically engineered salmon (S.Rept. 112-73), and this provision was not in the subsequently enacted P.L. 112-55. S. 1717 would have prohibited the sale of genetically altered salmon. On December 15, 2011, the Senate Commerce, Science, and Transportation Subcommittee on Oceans, Atmosphere, Fisheries, and Coast Guard held an oversight hearing on the environmental risks of genetically engineered fish. On May 24, 2012, S.Amdt. 2108 to S. 3187 was defeated, proposing to prohibit approval by FDA of genetically engineered fish unless NOAA concurred with such approval. No further action was taken on any of these bills by the 112<sup>th</sup> Congress.

## Author Information

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## Acknowledgments

CRS summer intern Rachel Borgatti prepared the initial draft of this document in 2004. Retired CRS specialist Eugene H. Buck and CRS analyst Tadlock Cowan also made important contributions to the report.

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<sup>48</sup> Maryland Natural Resources Code Ann. §4-11A-02 (2003).

<sup>49</sup> Washington Administrative Code 220-76-100 (2003).

<sup>50</sup> Oregon Administrative Rules 635-007-0595 (2004).

<sup>51</sup> Minn. Stat. §17.4982, 18B.285, §18B.01, 18F.01-.13 (2003)

<sup>52</sup> Wis. Stat. §146.60 (2002)

<sup>53</sup> California Fish & Game Code §15007 (2003) and Dept. of Fish and Game §671.1.

<sup>54</sup> AK Food & Drug Code §17.20.040 (2005)

<sup>55</sup> In response a group of 38 food-related organizations urged Congress not to interfere in the FDA regulatory process; see [http://www.bio.org/sites/default/files/20110802\\_fda\\_review.pdf](http://www.bio.org/sites/default/files/20110802_fda_review.pdf). A contrary opinion was expressed by Andrew Kimbrell and Colin O’Neill, “Biotechnology: US Congress Right to Halt GM Salmon,” *Nature*, v. 476, no. 283 (August 18, 2011): 283.

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